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Confirmation No.: 9352

Filed: 5 December 2003

For: SILCER COATINGS AND METHODS OF MANUFACTURE

Remarks

The Office Action mailed January 29, 2008 has been received and reviewed. Claims 1, 6, 14, 15, 26, and 27 having been amended, claims 5, 36, and 40-44 having been cancelled, without prejudice, and claim 45 having been added, the pending claims are claims 1-4, 6-35, 37-39, and 45. Reconsideration and withdrawal of the rejections are respectfully requested.

Applicants note with appreciation that claims 1-39 have been considered.

The claims have been amended to clarify that the ammonium-containing compound and silver-containing compound are in one solution that is coated onto a substrate (the solution is formed prior to coating) and dried. Furthermore, claims 1 and 15 have been amended to recite "drying the solution to form a coated substrate that is stable to at least one of visible light, ultraviolet light, electron beam, and gamma ray sterilization" and claim 27 has been amended to recite "drying the solution to form a coated substrate that does not darken upon exposure to visible light." Support can be found throughout the specification (e.g., page 1, lines 28-32, page 2, line 30, through page 3, line 5, and page 4, lines 28-34), and originally filed claims (e.g., claim 36). No new matter has been added.

Information Disclosure Statement

A Supplemental Information Disclosure Statement was submitted by Applicants on November 1, 2007. Applicants did not receive an initialed copy of page 2 of the 1449 form submitted with the Supplemental Information Disclosure Statement indicating that the listed documents were considered by the Examiner. For the Examiner's convenience, a copy of page 2 of the 1449 form is attached as EXHIBIT A.

Furthermore, a Supplemental Information Disclosure Statement was submitted by Applicants on June 5, 2007. The Examiner inadvertently initialed the description of the document (i.e., U.S. Patent Applications) and not the actual document. For the Examiner's convenience, a copy of page 2 of the 1449 form is attached as EXHIBIT B.

Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request

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that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Double Patenting Rejection

Claims 1-44 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of co-pending U.S. Patent Application No. 10/917,002. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 14 and 26 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The Examiner alleged that the claims are rendered indefinite by raising a question or doubt because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art.

Regarding claim 14, the Applicants respectfully submit that film is not necessarily generic to gauze and foam and incorporate by reference the arguments presented in the previous response. In the interest of expediting prosecution, however, claim 14 has been amended to remove "film" and a separate claim has been added (claim 45) to recite "film." It is respectfully submitted that this is not an admission that this is a proper rejection; rather, this has been done solely in the interest of expediting prosecution.

With respect to claim 26, it has been amended to remove the term "essentially" thereby rendering the rejection under 35 U.S.C. §112, second paragraph moot.

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The 35 U.S.C. §102 and §103 Rejections

The Examiner rejected claims 1, 2, 5, 9-14, 25, and 36 under 35 U.S.C. §102 as being anticipated by GB 769,799. The Examiner rejected claims 3, 4, 7, 8, and 37 under 35 U.S.C. §103 as being unpatentable over GB 769,799 in view of WO 02/43743. The Examiner rejected claim 6 under 35 U.S.C. §103 as being unpatentable over GB 769,799 in view of Murtfeldt (U.S. Patent No. 4,592,920). The Examiner rejected claims 15-24, 26, and 28 under 35 U.S.C. §103 as being unpatentable over the combination of GB 769,799, WO 02/43743 and Murtfeldt (U.S. Patent No. 4,592,920). The Examiner rejected claims 27, 28, and 33-35 under 35 U.S.C. §103 as being unpatentable over GB 769,799 combined with Murtfeldt (U.S. Patent No. 4,592,920). The Examiner rejected claims 29-32 and 39 under 35 U.S.C. §103 as being unpatentable over combined GB 769,799 and Murtfeldt (U.S. Patent No. 4,592,920) and further in view of WO 02/43743.

It is noted that claim 36, which recited "the composition of claim 1 stable" was only rejected under 35 U.S.C. §102 as being anticipated by GB 769,799. Each of the independent claims having been amended to recite that "the coated substrate is stable . . .", each of the §103 rejections has been rendered moot. Claim 1 having been amended to recite a specific list of silver compounds – silver carbonate, silver oxide, silver stearate, silver phosphate, silver thiocyanate – none of which are specifically disclosed by GB 769,799, the 35 U.S.C. §102 rejection over GB 769,799 is rendered moot. Insofar as any of these rejections might apply to the presently pending claims, they are respectfully traversed.

It is respectfully submitted that GB 769,799 is characterized inaccurately at page 5 of the Office Action (" . . . dipping or wetting the substrate surface with solution comprising aqueous solution of silver salt including silver nitrate, and ammonia compound to solubilize the silver salt, followed by drying the wet substrate. . . "); at page 7 of the Office Action (" . . . GB '799 disclosed ammonia added to the sparingly water soluble salt solution . . ."); and at pages 8-13 of the Office Action (" . . . coating an aqueous solution comprising sparingly water soluble silver salt and ammonia on the article followed by drying the article as disclosed by GB '799.") (several occurrences).

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The only possible example in GB 769,799 that can be characterized in this manner is Example 2, Treatment O, which discloses a formulation where AgCl is combined with aqueous ammonia to form a solution. However, two solutions are used in Treatment O, and the "[c]otton cloth treated according to Treatment "O" was not stable against discoloration by light" (page 7, lines 45-47).

GB 769,799 teaches that in order to make a photostable silver fabric, the silver salt and the photostabilizing metal salt need to be in the First solution and that the First solution should not contain ammonia. Further, GB 769,799 teaches that the silver salt and the photostabilizing metal salt need to be co-precipitated by the addition of a Second solution. That is, other than Treatment O in Example 2, which was indicated as a failure because it was "not stable against discoloration by light" (page 7, lines 45-57), there is no single "solution of silver salt . . . and ammonia compound"; rather, GB 769,799 discloses a method that uses multiple solutions: (1) a first solution containing a water-soluble silver salt and a water-soluble salt of a metal other than silver (the first salt); and (2) a second solution that includes two water soluble salts (the second and third salts) and ammonia or other water-soluble basic nitrogen compound.

The second salt in the second solution includes an anion of a sparingly water-soluble silver salt, but not silver (other than in Treatment O of Example 2, which includes AgCl). Thus, there is no silver-containing compound in the second solution (other than in "failed" Treatment O). The silver-containing compound and ammonia (or other basic nitrogen compound) are in two separate solutions that are applied sequentially to a substrate with mechanically removing excess solution (e.g., "squeezing, wringing, or wiping") between application of the two separate solutions.

There is no teaching or suggestion of combining these compounds prior to coating them on a substrate (e.g., claim 1 recites in part, providing a sparingly soluble silver-containing compound selected from the group consisting of silver carbonate, silver oxide, silver stearate, silver phosphate, silver thiocyanate, and combinations thereof, providing an ammonium-containing compound, combining the sparingly soluble silver-containing compound with the ammonium-containing compound to form an aqueous solution prior to coating on a substrate,

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and subsequently, coating the solution formed by combining the silver-containing compound and the ammonium-containing compound on a substrate). Each independent claim has been amended to clarify that the solution coated on the substrate is formed by combining the silver-containing compound (e.g., silver oxide) and the ammonium-containing compound (e.g., ammonium carbonate). This coating occurs subsequent to forming the solution with both the silver-containing compound and the ammonium-containing compound. This is neither taught nor suggested by GB 769,799. In fact, Treatment O of Example 2 of GB 269,799, which uses two solutions, one of which has a silver-containing compound and an ammonium-containing compound, is actually considered a failure because “[c]otton cloth treated according to Treatment ‘O’ was not stable against discoloration by light” (page 7, lines 45-47).

The Examiner stated at page 16 of the Office Action that “the features upon which applicant relies (i.e., single solution) are not recited in the rejected claim(s).” While it is true Applicants did not amend the claims in the previous response to recite literally “a single solution,” each independent claim was amended to recite that the two components of interest (the silver-containing compound, e.g., silver oxide, and the ammonium-containing compound, e.g., ammonium carbonate) were combined “to form an aqueous solution prior to coating on a substrate.”

The Examiner further stated at page 16 of the Office Action that although “the reference teaches mechanical drying, it is noticed that the expression ‘comprising’ of the claims’ language does not exclude mechanical drying.” Applicants agree and did not present the argument about mechanical drying previously with the intention of implying that Applicants’ claims did not require such step. This mechanically removing excess solution (e.g., “squeezing, wringing, or wiping”) between the application of the silver-containing and ammonium-containing components in two separate solutions was emphasized in an effort to further demonstrate the distinction between GB 769,799 and Applicants’ invention, which recites combining the recited components before applying to a substrate, then applying and drying to form a stable substrate.

It would not be obvious to combine the silver-containing and ammonium-containing compounds prior to coating, as recited in Applicants’ claims, based on the teachings of any of the

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cited documents, in any combination. Applicants have done this with Example 2 Treatment A, of GB 769,799 by combining the First solution (5 g AgNO_3 , 5g $\text{Mg}(\text{NO}_3)_2 \cdot 6\text{H}_2\text{O}$, 1000 mL H_2O) with the Second solution (3 g NaCl , 5g $\text{Na}_2\text{PO}_4 \cdot 12\text{H}_2\text{O}$, 200 mL $\text{NH}_3(\text{Aq})$ and 800 mL H_2O). Prior to mixing, both solutions were clear, and upon mixing a white precipitate formed. The formation of the white precipitate indicates that the salts are not compatible in a single solution. This mixture is therefore not suitable for treating cotton because the precipitated particles would not incorporate properly into the interstices of the cotton fiber. It is not clear why the ammonia is included in the Second solution. While it is true that ammonia will solubilize silver salts (for example, AgCl), the ammonia comes into contact with the AgCl in Treatment A at the very moment when the inventor is also attempting to co-precipitate AgCl and MgPO_4 . Perhaps, the ammonia acts more as a stabilizer and less as a solubilizer. The ammonia probably does not completely vaporize, but some of it continues to remain complexed with the AgCl , and contributes to the AgCl photostability. If desired, Applicants can provide a Declaration providing the details of this experiment.

Thus, one of skill in the art would not combine the two separate solutions of GB 769,799 prior to coating on a substrate. GB 769,799 teaches that in order to make a photostable silver fabric, the silver salt and the photostabilizing metal salt need to be in the First solution and that the First solution should not contain ammonia. Further, GB 769,799 teaches that the silver salt and the photostabilizing metal salt need to be co-precipitated by the addition of a Second solution.

In fact, Example 2, Treatment O, of GB 269,799, actually teaches away from Applicants' invention in that it discloses a formulation where AgCl is combined with aqueous ammonia to form a solution, which "was not stable against discoloration by light"(page 7, lines 45-47).

Nothing in WO 02/43743 or in U.S. Pat. No. 4,592,920 teaches or suggests that which is missing from GB 769,799. For example, neither document teaches or suggests combining the recited silver-containing and ammonium-containing components prior to application to a substrate.

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WO 02/43743 discloses that a polymer is first brought into contact with the silver in an alcohol/water (i.e., **organic solution** with 50% or more alcohol; page 6, line 21) so as to avoid hydration of the polymer (page 6, lines 15-18). During or after the period wherein the polymer is subjected to the organic solution, it is subjected to one or more photostabilizers (page 7, lines 4-5). Although an aqueous ammonium salt solution may be added to the treatment mixture (i.e., the silver-containing organic solution with polymer), the resulting solution would still need to limit the amount of water to 50% or less to avoid hydration of the polymer, according to the teaching at page 6, lines 15-22 of WO 02/43743.

In contrast, Applicants first combine the silver-containing compound with an ammonium containing compound to form an **aqueous solution**. Although there is no specific reference to the amount of water, all the examples include only water as the liquid carrier with no alcohols or other organic liquids included. The large percentage of water used in Applicants' aqueous treatment solutions would not be acceptable for use in the treatment solutions of WO 02/43743 because it would hydrate the polymer. In Applicants' method, after the silver and ammonium compounds are combined in an aqueous solution, then the silver/ammonium solution is brought into contact with the polymer substrate.

WO 02/43743 discloses medical materials containing silver salts, with a laundry list of silver salts (page 5, line 28 through page 6, line 4). WO 02/43743 specifies as "appropriate sources of silver" those that are water and/or alcohol soluble (page 6, lines 3-4). Although the list includes, for example, silver carbonate (page 5, line 29 through page 6, line 1), there is no preference for sparingly soluble silver-containing compounds, as defined by Applicants at page 3, lines 1-3. Furthermore, WO 02/43743 does not teach or suggest use of silver oxide, as recited in Applicants' independent claims 15 and 27. The selection of silver-containing compounds that are sparingly soluble in water, particularly silver oxide, contributes to a product that releases the silver compound over time, rather than all at once (upon contact with a wound). This problem and solution were not recognized by WO 02/43743.

Using a sparingly soluble silver-containing compound makes it difficult to process using aqueous solutions. Applicants have solved this problem by using an ammonium-containing

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compound to assist in dissolution of the sparingly soluble silver-containing compound in water. This problem and solution are not recognized by WO 02/43743.

Furthermore, WO 02/43743 discloses an example at page 8 using an AQUACEL wound dressing, commercially available from ConvaTec, which is treated with a silver nitrate solution containing silver chloride in an amount of between 0.01 and 50%. The resultant product is said to be photostable, which is defined at page 7, lines 28-29 as "[c]ontrolled colour change to a desired colour with minimal change thereafter." Applicants have tested a commercially available product believed to be similar to this material. This test appears as Comparative Example D at page 19 of WO 2006/113052, and demonstrates that a commercially available product from Conva Tec, referred to as AQUACEL Ag, which contains silver chloride/silver alginate, undergoes an undesirable color change upon exposure to fluorescent light. Thus, this product is not "stable" as defined by Applicants' specification at page 4, lines 28-29 ("coated compositions do not darken upon exposure to visible light").

It is respectfully submitted that GB 769,799, as well as the combination of WO 02/43743 and/or U.S. Pat. No. 4,592,920 in any manner with GB 769,799, fails to teach or suggest all of the features of Applicants' claims. Withdrawal of the 35 U.S.C. §102 and §103 rejections is respectfully requested.

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Summary

It is respectfully submitted that the pending claims 1-4, 6-35, 37-39, and 45 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23rd day of April, 2008, at 2:30pm (Eastern Time).

By:

Name: Ann M. Mueting